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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,196	03/23/2000	ROGER JOHN DALY	1871-129	8868

24353 7590 11/05/2002

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/05/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/509,196	DALY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,5-7 and 19-31 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 1,5-7 and 19-31 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a)  The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 03, 2002 has been entered.

### ***Response to Amendment***

2. Claim 1 has been amended and claims 22-31 have been added as requested in the amendment of Paper No. 20, filed on August 20, 2002. Claims 1, 5-7, 19-31 are pending in the instant application.
3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on April 03, 2002, Paper No. 14, have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 101***

6. Claims 1, 5-7, 19-31 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for

reasons of record as applied to claims 1-7 in section 9 of Paper No. 12. Briefly, the instant application has provided a description of an isolated polynucleotide molecule encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance.

Applicant submits that “Grb7 family of SH2 domain containing proteins have been shown to be associated with oesophageal carcinoma [...]primary gastric cancer [...] and breast cancer” (page 8, last paragraph and page 9, first paragraph of the Response). Also “Grb7 has been shown to bind to Human EGF receptor 2, known to play an important role in a number of tumors including breast cancer” (page 9, second paragraph). Therefore, “identification of a protein which binds to the Grb7 family of proteins, including Grb7 and Grb14, is an important finding” (page 9, last paragraph). However, by analyzing the fact that “the new sequence is expressed in all tissues except kidney cells” (page 10, second paragraph), one skilled in the art would reasonably conclude that the novel polypeptide 2.2412 cannot possibly be a specific marker for any cancer cells due to the general pattern of its tissue distribution. Therefore, based on the example of broad pattern of expression, the assertion made in the instant specification that “Detection of the protein encoded by the cDNA 2.2412 in a sample should provide a useful tumor marker and prognostic indicator for [these] cancers” (page 5, lines 13-19 of the instant specification) is not persuasive.

Applicant’s reliance on the post-filing date publications showing that the protein encoded by the claimed nucleotide sequence “is an antigen specific to a number of types of cancers” has not been found to be persuasive for the following reasons. At the time the instant application was filed no specific, substantial and credible utility for the claimed polynucleotides was presented.

There was no evidence of record in the instant specification, which credibly associates the instant DNA or encoded protein with any human cancers. Applicant's own statement confirms that the novel 2.2412 is broadly expressed in all normal tissues, and, consequently, cannot be specific for any tissue except for normal kidney cells, see the explanation earlier. The belief that a novel protein encoded by the claimed polynucleotide is a candidate effector protein for the Grb7 proteins, which maybe associated with cancer, does not make the instant DNA or encoded protein diagnostic of cancer. Therefore, in the absence of knowledge of biological activity of the protein, at the time of the invention, one would not be able to diagnose, prevent or treat cancer or any other condition or disease as implied by the specification. Any further subsequent characterization of the claimed DNA and encoded protein, which can and will lead to the discovery of a specific and substantial credible utility is considered to part of the act of invention. Unless credible specific and substantial utility of the claimed compound is disclosed in the specification as filed, Applicant's claimed invention is incomplete. “[A] patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”. *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966).

#### ***Claim Rejections - 35 USC § 112***

7. Claims 1, 5-7, 19-31 are also rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-7 in section 10 of Paper No. 12.
8. Claims 1, 5-7, 20, 22-28 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 1-3 in section 12 of Paper No. 12.

***Conclusion***

9. No claim is allowed.
10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.

November 1, 2002

OV



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800